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Robertson et al.

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[54] **STERILE PACKAGING METHOD FOR SURGICAL DEVICES**

[75] Inventors: **Gordon W. Robertson**, Larkin Twp., Midland County; **Lee H. Breasbois**, Tittabawassee Twp., Saginaw County, both of Mich.

[73] Assignee: **Dow Corning Corporation**, Midland, Mich.

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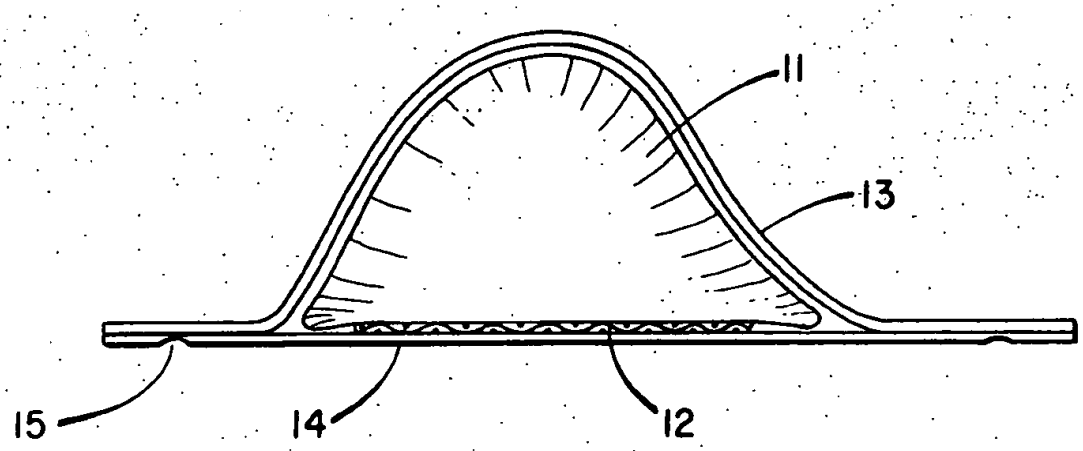
Primary Examiner—Alfred L. Leavitt
Assistant Examiner—Caleb Weston
Attorney—Robert F. Fleming, Jr., Howard W. Hermann et al.

[57] **ABSTRACT**

Method of sterile packaging of a surgical device comprising heat forming a sheet of Teflon FEP to form a blister having shape and dimensions of the device, placing the device in the blister, covering it with a second sheet of Teflon FEP, heat sealing the edges of the package and dry heat sterilizing the packaged device.

4 Claims, 2 Drawing Figures



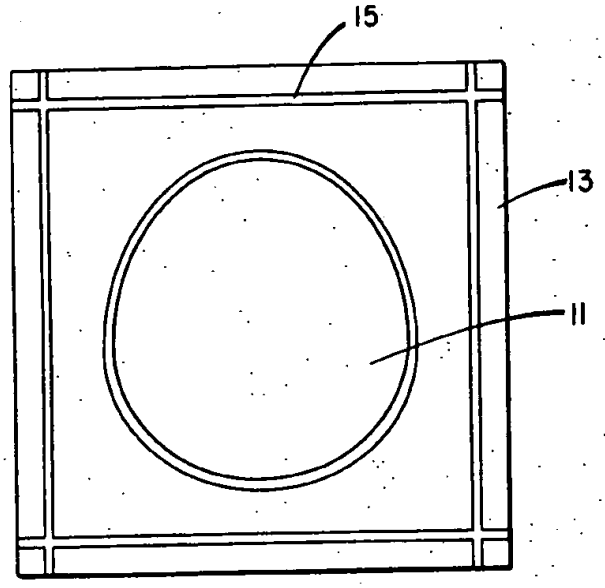


Fig. 1

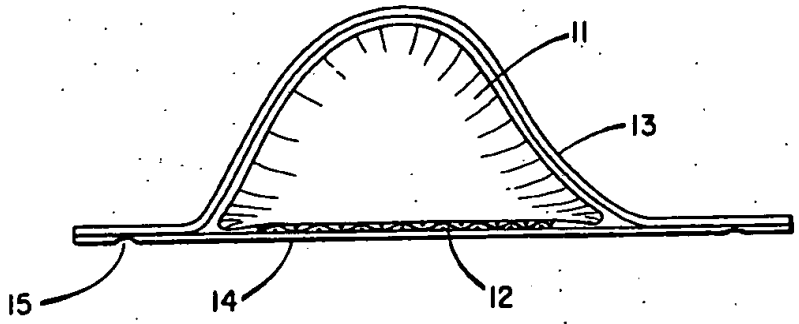


Fig. 2

INVENTORS
GORDON W. ROBERTSON
LEE H. BREASBOIS
BY Howard W. Hermann
ATTORNEY

STERILE PACKAGING METHOD FOR SURGICAL DEVICES

BACKGROUND OF THE INVENTION

This invention relates to the packaging of surgical devices, and more particularly relates to methods of packaging such devices to maintain the devices sterile until used.

It is well known that maintenance of sterility of surgical devices is considered a necessity. Various methods of sterilization and maintenance of sterility after sterilization have been in use by the medical profession and paramedical personnel. By far the most common technique is the use of the autoclave to sterilize parts by means of exposure to pressurized steam for a predetermined period of time. This is generally done just prior to use in order to assure sterility at time of use and, of course, involves expenditure of time and labor. To members of a surgical team this is at best an inconvenient approach to the problem in view of the fact that it may not be known with certainty what devices will be needed in the course of an operation.

Particularly in the case of surgical implants or other devices which are used as they come from the manufacturer and are not meant to be reused, there has been a trend toward sterilization by the manufacturer and packaging aimed at maintaining sterility until use. This has generally been accomplished by sterilizing the device by using steam or ethylene oxide, and presterilizing the package as well. The sterilized device is then placed in the sterilized package and the package is sealed. Assuming no contamination of device or package interior during handling after sterilization and assuming the package acts as a complete barrier to possible future contamination, a sterile product will then be available for immediate use upon opening of the package. There are objections to this technique, however, in the amount of labor required in handling and the lack of insurance against contamination by handling after sterilization. Sterilization in the package has been accomplished by using a porous package through which steam or ethylene oxide can be passed. This approach is fraught with danger of contamination by organisms subsequently passing the porous package.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a method of sterile packaging which is more economical in terms of time and labor than heretofore known methods and which eliminates other disadvantages of the prior art.

In accordance with the above and other objects there is provided by the present invention a method of sterile packaging in which sterilization is accomplished in the final package and the package remains sealed, thereby retaining sterility, until the package is opened for use. Teflon FEP fluorocarbon film, a copolymer of tetrafluoroethylene and hexafluoropropylene, is used to form a blister package which is heat sealed around its edges after placement of the device to be packaged into the blister. The closed package is then subjected to heat at a minimum of about 250° F. and a maximum of about 490° F. for sufficient time to effect sterilization of the package contents.

BRIEF DESCRIPTION OF THE DRAWING

The invention will become better understood and other objects and advantages thereof will become apparent to those skilled in the art from a consideration of the following detailed description when read in conjunction with the accompanying drawings wherein:

FIG. 1 is a topview showing a mammary prosthesis packaged in accordance with the present invention; and

FIG. 2 is a sideview partially in cross-section of the embodiment shown in FIG. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings there is shown a mammary prosthesis 11 of the type disclosed in U.S. Pat. No. 3,293,663 issued Dec. 27, 1966 to Thomas D. Cronin. The prosthesis 11 is a surgically implantable body of silicone gel enclosed in a silicone rubber envelope having tissue ingrowth means 12 such as open mesh fabric or felt affixed to the rear portion thereof.

The prosthesis 11 is packaged in a blister package comprising a first sheet 13 of Teflon FEP having a cavity formed therein approximating the exterior dimensions of the prosthesis 11 and a second sheet 14 of Teflon FEP which forms the closure of the cavity in the first sheet 13. The two sheets are bonded together and sealed by a heat seal 15 around the entire periphery of the package.

Teflon FEP is a copolymer of tetrafluoroethylene and hexafluoroethylene available from E.I. Du Pont De Nemours & Co., Wilmington, Delaware. The material has a melting point of 500°–535° F., a tensile strength of about 3,000 p.s.i., tensile elongation of about 300 percent, and tensile modulus of about 70,000 p.s.i. Other physical and thermal properties are described in Du Pont Technical Information Bulletin T-2B concerning "Du Pont Teflon FEP Fluorocarbon Film" and chemical properties are described in a similarly identified publication number T-3B.

The cavity for the prosthesis 11 is preferably formed in a sheet of Teflon FEP fluorocarbon film which is of 10 mil thickness. The cavity is preferably formed by vacuum forming techniques using a mold preheated between 200° F. and 300° F. and heating the film to 475° to 490° F. before vacuum drawing into the female mold. Pressure thermoforming techniques can also be used to mold the cavity.

After forming the sheet 13 with the cavity, the prosthesis 11 is placed in the cavity and the second sheet 14 is placed over the cavity opening. The second sheet is preferably a sheet of Teflon FEP fluorocarbon film which is of 5 mil thickness. The two sheets 13 and 14 are then fused together around their periphery by means of a heated bar or other known heat sealing means to completely seal the prosthesis in the cavity. The heat sealing is accomplished by heating the material to its melting point while the two sheets are held in contact. The hot bar in the preferred embodiment is of ⅛ inch width and is heated to approximately 625° F. The necessary dwell time is shortened by placing the heated bar against the thinner sheet, or alternatively, double heated bars can be used to further shorten the necessary dwell time.

After the package has been sealed it is placed in an oven heated to at least 250° F. and not greater than about 490° F. (because melting of the package can occur) for sufficient time to sterilize the package contents. Since necessary time is dependent upon the

thickness of the package, the volume of the blister, and the termal conductivity and reflectivity of the surgical device contained therein, no specific limits can be placed on sterilization time. However, for the mammary prosthesis described herein the present preferred sterilization cycle is maintenance of temperature between 280° F. and 290° F. for 5 hours. Dry heat is preferred to steam for ease in handling, although steam can also be used.

After completion of the heating cycle the surgical device is ready for use without further sterilization, even after storage for an extended period of time. The Teflon FEP is an effective sterilization barrier. The specific method described above should be considered as illustrative only, and it should be realized that the mammary prosthesis was chosen only as an example of surgical devices which can be packaged in the manner described. One variation of the method described which is useful in further minimizing contamination after the package has finally been opened for use is the wrapping of the device to be packaged in a thin sheet of material which is thermally stable at the sterilization temperatures to be used, before the device is placed in the cavity of the sheet 13. The thin sheet can be, for example, a further sheet of Teflon FEP fluorocarbon film having 0.5 mil thickness, which drapes easily to conform to the shape of the device being packaged. The thin sheet becomes sterile with the device and allows handling of the device in order to remove it from the package without touching the device itself.

Obviously other variations of the method described will become obvious to those skilled in the art from a reading of the foregoing. It is to be understood, therefore, that within the scope of the appended claims the invention may be practiced otherwise than as specifically described.

That which is claimed is:

1. A method of sterile packaging of medical devices which comprises in sequence:

heating a first sheet of Teflon FEP fluorocarbon film and forming said sheet in a female mold to form a cavity in said sheet, said cavity having overall length and width dimensions at least equivalent to the length and width dimensions of the device to be packaged,

placing a medical device in said cavity in said first sheet,

placing a second sheet of Teflon FEP fluorocarbon film over said cavity in said first sheet with the edges of said sheets in contact with one another around the entire periphery of the cavity,

heat bonding the entire periphery of the two sheets to form a sealed chamber with said device located therein, and

applying heat at a temperature of at least 250°F. but below the melting temperature of said Teflon FEP fluorocarbon film to the heat sealed package for a sufficient length of time to sterilize the device sealed therein.

2. The method as defined in claim 1 wherein said cavity is formed by drawing said first sheet into the mold by use of vacuum.

3. The method as defined in claim 1 and further comprising prior to the step of placing the device in the cavity, wrapping the device in a drapable sheet of material which is heat stable at the temperatures used during the heat sterilization step.

4. The method defined in claim 3 wherein said drapable sheet material is also Teflon FEP fluorocarbon film.

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